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(71) Applicant: CORE MEDICAL, INC. [US/US]; 743 Pastoria Avenue, Sunnyvale, CA 94086-2918 (US).

(72) Inventor: GINN, Richard, S.; 297 Marti Way, San Jose, CA 95136 (US).

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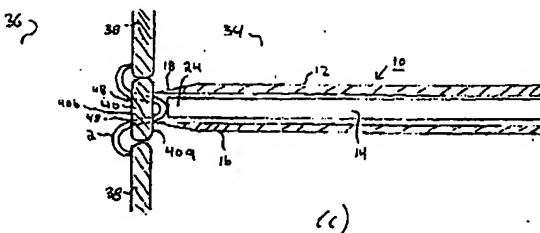
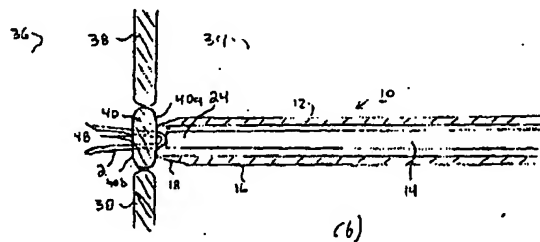
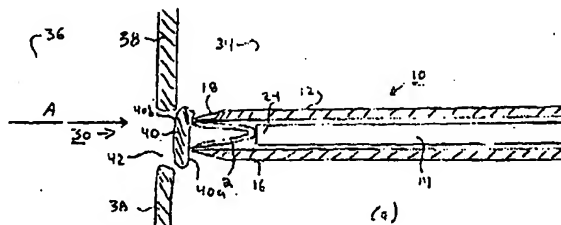
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(54) Title: CLIP APPARATUS FOR CLOSING SEPTAL DEFECTS AND METHODS OF USE



(57) Abstract: A device for closing a septal defect, such as a patent foramen ovale, includes a clip formed from a superelastic material that is inserted into a septum wall of a heart. The clip is advanced through a patient's vasculature, e.g., within a delivery apparatus, until the clip is disposed within a first chamber adjacent the septal defect. Tines of the clip are directed through a flap of tissue of the septal defect until the tines of the clip are disposed within a second opposing chamber. The clip then transforms into its relaxed state, wherein the tines of the clip engage with a surface of the second chamber, thereby substantially closing the septal opening.

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CLIP APPARATUS FOR CLOSING SEPTAL DEFECTS AND METHODS OF USE**FIELD OF THE INVENTION**

The present invention relates generally to apparatus and methods for treating septal
5 defects, and more particularly to apparatus and methods for closing a patent foramen ovale or
other septal defect.

BACKGROUND

During development of a fetus in utero, blood is generally oxygenated by the mother's
10 placenta, not the fetus' developing lungs. Most of the fetus' circulation is shunted away from
the lungs through specialized vessels or foramens that are open during fetal life, but generally
close shortly after birth. Occasionally, however, these foramen fail to close and create
hemodynamic problems, which may ultimately prove fatal unless treated.

One defect that may occur is a patent foramen ovale ("PFO"), which may occur
15 between the left and right atria of the heart. During fetal life, an opening called the foramen
ovale allows blood to pass directly from the right atrium to the left atrium (bypassing the
lungs). Thus, oxygenated blood from the placenta may travel through the vena cava into the
right atrium, through the foramen ovale into the left atrium, and from there into the left
ventricle for delivery via the aorta to the fetus' body. After birth, with pulmonary circulation
20 established, the increased left atrial blood flow and pressure causes the functional closure of
the foramen ovale. This closure is then followed by the anatomical closure of the foramen
ovale.

In some humans, however, the foramen ovale fails to completely close. This condition
can pose serious health risks for the individual, particularly if the individual has other heart
25 abnormalities. For example, recent studies suggest an association between the presence of a
patent foramen ovale and the risk of paradoxical embolism or stroke. See P. Lechat J et al.,
Prevalence of Patent Foramen ovale in Patients with Stroke, N. Engl. J. Med. 1988;318: 1148-
1152.

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Still other septal defects may occur within a septum between the various chambers of the heart, such as atrial-septal defects (ASDs), ventricular-septal defects (VSDs), and the like. To close such defects, open heart surgery may be performed to ligate and close the defect. Such procedures are obviously highly invasive and pose substantial morbidity and mortality risks.

Alternatively, catheter-based procedures have been suggested. These may involve introducing umbrella or disk-like structures into the heart that include opposing expandable structures connected by a hub or waist. Generally, the device is inserted through the defect, and the expandable structures are deployed on either side of the septum to secure the tissue surrounding the defect between the umbrella or disk-like structure in an attempt to seal and close the defect. Such devices, however, involve frame structures that often support membranes, either of which may fail during the life of the patient being treated, opening the defect and/or releasing segments of the structure within the patient's heart.

Accordingly, apparatus and methods for closing septal defects, and in particular a patent foramen ovale, would be considered useful.

20

SUMMARY OF THE INVENTION

The present invention is directed to apparatus and methods for closing septal defects, including, but not limited to, a patent foramen ovale.

In a first aspect of the invention, an apparatus for closing a septal defect includes a clip formed from a elastic material having at least two penetrating tines and an opposing retaining end. The clip is biased so as to project the at least two penetrating tines distal to the opposing retaining end, wherein when the bias is removed, the at least two penetrating tines move laterally apart from one another.

In accordance with another aspect of the present invention, a delivery apparatus for delivering a clip, such as that described above, is provided that includes an outer catheter and

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a pusher member that are slidably coupled to one another. The catheter may be a tubular member including proximal and distal ends and a lumen therebetween, the distal end having a size for insertion into a blood vessel or other body lumen. The clip may be carried within the lumen of the outer catheter, preferably, with the tines disposed distally to the retaining end.

5 The pusher member may be an inner catheter or other elongate member that is disposed within the lumen of the outer catheter. The pusher member may include a distal end that may be disposed proximate the retaining end of the clip, the pusher member being movable axially relative to the tubular member for ejecting the clip distally from the lumen.

10 An actuator may be provided on the proximal end of the tubular member and/or the pusher member for advancing the pusher member relative to the tubular member. Preferably, the actuator may limit advancement of the pusher member.

15 In a further alternative, the delivery apparatus may include an imaging device including an imaging element associated with the distal end of the tubular member for imaging near or beyond the distal end of the tubular member. For example, the imaging device may be an angioscope or ultrasound device that may be received within a lumen of the tubular member or may be a separate device that may introduced independently into the patient but used in conjunction with the delivery apparatus during a procedure.

20 In another alternative, the clip has a single tine and an opposing retaining end. The clip is biased so as to project the single tine distal to the opposing retaining end. When the bias is removed, the clip transforms into a geometric shape such as a "V", "U", "S", or "L". The opposing retaining end may have an optional head to prevent the clip from completely passing through the septum wall of a heart.

25 In accordance with yet another aspect of the present invention, a method is provided for closing a patent foramen ovale or other septal defect within a patient's heart. Generally, the septal defect includes one or more flaps of tissue partially detached from a septum wall between first and second chambers of the heart, the flap(s) of tissue and surrounding tissue of the septum wall defining a septal opening through the septum wall.

A clip, such as that described above, is advanced, in a stressed state, through the patient's vasculature until the clip is disposed adjacent to the septal opening. The tines of the

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clip penetrate the flap of tissue and pass into the second chamber of the heart. After the clip has penetrated the flap of tissue (i.e., septal defect), the clip transitions to its relaxed state so as to at least partially close the septal opening.

It is an object of the invention to provide a clip apparatus for the closure of septal defects, such as a patent foramen ovale. It is a further object of the invention to provide a delivery device for the delivery of the clip apparatus to the defect area. It is yet a further object of the invention to provide a method of closing a patent foramen ovale using the clip apparatus. Other objects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a clip apparatus showing the clip in a stressed state.

FIG. 2 is a cross-sectional view of the clip shown in FIG. 1 with the clip in a relaxed state.

FIG. 3 is a cross-sectional view of a delivery apparatus showing a pusher member and a clip contained within a lumen of the delivery apparatus.

FIG. 4 is a cross-sectional view of a heart including a septal foramen ovale in a septum wall of the heart. The delivery apparatus of FIG. 3 is shown being advanced through the aortic arch.

FIG. 5 is a perspective detail view of the septal defect shown in FIG. 4. A flap of tissue, which is partially attached to the septum, has been pierced by the clip in its stressed state.

FIG. 6 is a perspective detail view of the septal defect shown in FIG. 4 after deployment of the clip apparatus. The flap of tissue has closed the opening after the clip has transitioned to its relaxed state.

FIG. 7(a) is a cross-sectional view of the septum wall and delivery device, showing a method for closing the septal defect shown in FIGS. 4-6. The delivery device is shown adjacent to the flap of tissue.

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FIG. 7(b) is a cross-sectional view of the septum wall and delivery device, showing a method for closing the septal defect shown in FIGS. 4-6. The pusher member has deployed the clip through the flap of tissue.

FIG. 7(c) is a cross-sectional view of the septum wall and delivery device, showing a method for closing the septal defect shown in FIGS. 4-6. The clip has transitioned to its relaxed state and closed the septal defect.

FIG. 8 is a perspective view of a clip according to a separate preferred aspect of the invention. The clip is shown in its stressed state.

FIG. 9 is a perspective view of the clip shown in FIG. 8 with the clip in its relaxed state.

FIG. 10 is a cross-sectional view of the septum wall showing a hole-type septal defect. The clip is shown in its stressed state.

FIG. 11 is a cross-sectional view of the septum wall showing a hole-type septal defect. The clip is shown in its relaxed state.

FIG. 12 is a cross-sectional view of the septum wall showing a hole-type septal defect. A clip having a single tine is shown in its relaxed state.

FIG. 13 is a cross-sectional view of the septum wall showing a hole-type septal defect. A clip having a single tine is shown in its relaxed state.

FIG. 14 is a cross-sectional view of the septum wall showing a hole-type septal defect. A clip having a single tine is shown in its relaxed state.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figures 1 and 2 illustrate a first preferred embodiment of a clip 2 that is used for closing a septal defect (i.e., PFO, ASA, VSA), in accordance with the present invention. The clip 2 includes two penetrating tines 4 that are connected to one another via an opposing retaining end 6. The tips 8 of the tines 4 are sharpened to aid in penetrating tissue. In Figure 1, the clip 2 is shown in its stressed state. In this regard, the clip 2 may be made from an elastic material, such as stainless steel, and preferably, a superelastic material. Alternatively, the clip 2 may be formed from a shape memory alloy, one example being NITINOL. Of

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course, other bio-compatible elastic or superelastic materials may also be employed. The clip 2 is maintained in its stressed state by restraining the tines 4 from expanding outward. In this manner a biasing force is applied to the clip 2. The tines 4 of the clip 2 project distally from the retaining end 6, as is shown, for example, in Figure 1. The tines 4 preferably are
5 restrained by using a delivery apparatus 10, such as a catheter or the like (discussed in more detail below). Preferably, in its stressed state, the clip 2 has the shape of a "U" or a "V", as is shown, for example, in Figure 1.

Figure 2 illustrates the clip 2 in its relaxed state. Without the application of the biasing force, the clip 2 transitions to its related configuration wherein the angle α between
10 the two tines 4 increases. The tines 4 also move laterally away from one another, as is shown, for example, in Figure 2. In addition, portions of the tines 4 closest to the tips 8 may optionally inflect back upon themselves. In one preferred embodiment, in the final relaxed configuration, the clip 2 preferably has the shape of a "W", as is shown, for example, in
Figure 2.

15 Depending on the type and nature of the septal defect, the clip 2 may have variations in its design. For example, the length of the tines 4 may be chosen depending on the size of the opening 42. If the opening is larger, longer tines 4 may be used. Similarly, a larger opening 42 may require a greater expansion angle α for the clip. Other variations may also be present, such as the degree of inflection, if any, in the ends of the tines 4 nearest the tips 8.
20 The clip 2 may be made of one piece of material or, alternatively, multiple segments.

Referring now to Figure 3, a delivery apparatus 10 generally includes an outer catheter or tubular member 12, and an inner catheter or pusher member 14. The outer catheter 12 includes a proximal end (not shown), and a distal end 16 having a size suitable for insertion into a blood vessel or other body lumen (not shown). The distal end 16 preferably has a
25 tapered or rounded tip 18, e.g., for facilitating substantial atraumatic advancement of the delivery apparatus 10 through the patient's vasculature. The outer catheter 12 also includes a lumen 20 therein that extends between proximal and distal ends 16. As shown in Figure 3, the clip 2 is contained within the lumen 20 of the outer catheter 12. The outer catheter 12 provides the biasing force to keep the clip 2 in its stressed state.

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In one preferred embodiment of the invention, the outer tubular member 12 may include one or more axially disposed grooves 22 (one is shown in Figure 3) within the inner surface that engages with the tine(s) 4 of the clip 2. The groove(s) 22 may serve as a guide for the clip 2 so that the orientation of the clip 2 is maintained during delivery. In this regard, the clip 2 may not rotate into a different orientation as it is ejected from the outer catheter 12.

The pusher member 14 includes a proximal end (not shown) and a distal end 24 having a size such that the pusher member 14 may be slidably disposed within the lumen 20 of the outer catheter 12. The distal end 24 may be disposed proximal to the retaining end 6 of the clip 2, and the pusher member 14 may be moveable axially relative to the outer catheter 12 for ejecting the clip 2 distally from the lumen 20, as is described more fully below.

Optionally, the distal end 24 of the pusher member 14 may contain a notch 26 that engages with the retaining end 6 of the clip 2 for assisting in orienting of the clip 2. The notch 26 may prevent the rotation of the clip 2, or alternatively, aid in rotating the clip 2 (through rotation of the pusher member 14) for proper orientation. The notch 26 may be present without or in addition to the groove(s) 22.

An actuator, e.g., a handle device (not shown), may be provided on the proximal end of the outer catheter 12 and/or the pusher member 14.

Use of the clip 2 for closing a septal defect 30 is shown in conjunction with Figures 4-7(c), 10, and 11. Figure 4 generally shows a heart 32 of a patient, including heart chambers 34, 36 separated by a septum wall 38. The septal defect 30, which may be a PFO, ASD, VSD and the like, is shown in the septum wall 38. As best seen in Figures 5 and 6, the septal defect 30 may include a flap of tissue 40 adjacent to an opening 42 in the septum wall 38. Figures 10 and 11 illustrate another septal defect 30 wherein the defect is a hole-type of structure 52, e.g., extending laterally through the septum wall 38.

The delivery apparatus 10, with the clip 2 therein, may be introduced into the patient's vasculature, e.g., from a percutaneous entry site in a peripheral vessel, such as the femoral vein, jugular vein, and the like (not shown). The distal end of the outer catheter 12, including the clip 2, may be advanced endoluminally within the patient's vasculature, e.g., through the vena cava 46 (inferior or superior) and into the heart 32 until the distal end 16 is disposed

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within the chamber 34, which is shown in Figure 4 to be the right atrium. Alternatively, the clip 2 may be introduced using an arterial approach as is commonly known in the art.

With particular reference to Figures 5, 6, and 7(a)-(c), the distal end 16 of the delivery apparatus 10 may be advanced into contact with a proximal surface 40a of the flap of tissue 40, e.g., such that the flap of tissue 40 is disposed proximate the septal opening 42, as shown in Figure 7(a). The pusher member 14 may be advanced distally relative to the outer catheter 12, thereby piercing the tines 4 of the clip 2 through the flap of tissue 40 until a portion of the tines 4 of the clip 2 are located within the second chamber 36 located on the opposing side of the septum wall 38, thereby creating punctures 48 for each tine 4. The penetrating tips 8 on the tines 4 of the clip are preferably sharp enough to facilitate piercing and passing of the tines 4 through the flap of tissue 40.

Preferably, the pusher member 14 is advanced distally to aid in pushing the tines 4 of the clip 2 through the flap of tissue 40. The pusher member 14 preferably pushes until the clip 2 cannot advance further through the flap of tissue 40 (i.e., the retaining end 6 of the clip 2 prevents further advancement). This may be accomplished by using an actuator (not shown) on the delivery apparatus 10 that permits controlled advancement of the pusher member 14. For example, the actuator may allow the distal end 24 of the pusher member 14 to be disposed at a location within or external to the distal tip 18 of the outer catheter 12.

Figure 7(b) shows the clip 2, still in its stressed state, puncturing the flap of tissue 40. The nature of the material of the clip 2 is such that the clip 2 remains in the stressed state as the tines 4 pierce the flap of tissue 40. After the clip 2 has passed through the flap of tissue 40, the clip 2 begins its transformation from the stressed state to the relaxed state shown, for example, in Figure 2. Figure 7(c) shows the clip 2 after it has passed into the relaxed state. In this embodiment, the tips 8 of the tines 4 have inflected back in the direction of the retaining end 6 of the clip 2. In doing so, the tips 8 of the clip 2 preferably engage with the septum wall 38 on opposing sides of the flap of tissue 40. While it is preferable that both tips 8 be engaged with the septum wall 38 to properly close the opening 42, it may still be possible to close the opening 42 if only one of the tips 8 engages with the septum wall 38.

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As best seen in Figure 6, in which a perspective detail view of the region of the septum wall 38 having the septal defect 30 is shown, the opening 42 between the first and second chambers 34, 36 has been eliminated by the placement of the clip 2 in the flap of tissue 40. By engaging with the septum wall 38, the tips 8 of the clip 2 may prevent the flap of tissue 40 from moving proximate to the septum wall 38 in the first chamber 34 (as is shown in Figure 7(a)).

Figures 8 and 9 show an alternative preferred embodiment of the clip 2 wherein the clip 2 has four tines 4 as opposed to the two tines 4 shown in Figures 1-7(c), 10, and 11. Figure 8 shows the clip 2 in a stressed state while Figure 9 shows the clip 2 in a relaxed state. The additional tines 4 may increase the chances that one or more tines 4 will properly be secured to the septum wall 38 upon deployment. While clips 2 having two and four tines 4 have been specifically disclosed herein, it should be understood that the clip 2 may have any number of tines 4 in excess of one, including even and odd numbers of tines 4.

It will be appreciated by those skilled in the art that the procedure described herein may be monitored in a variety of ways. For example, the delivery apparatus 10 may include an imaging device 50 (Figures 5 and 6), such as an angioscope or other fiber optic device, intravascular ultrasound ("IVUS") device, and the like (not shown). The device may be provided on the distal end 16 of the outer catheter 12, e.g., attached to or adjacent the distal tip 18 or advanceable from a lumen (not shown) therein. In a further alternative, external imaging may be used, either alone or in conjunction with direct visualization. For example, the clip 2, the outer catheter 12, and/or the pusher member 14 may include radiopaque markers (not shown) at predetermined locations that may be observed using fluoroscopy and the like.

Figures 10 and 11 illustrate a preferred embodiment of the clip 2, wherein in its relaxed state (shown in Figure 11), the tines 4 of the clip 2 lie substantially flat against the septum wall 38. This embodiment may be preferred for several reasons. First, a larger portion of the tines 4 may be in contact with the septum wall 38, giving the clip 2 a more secure hold to the flap(s) of tissue 40. Second, since at least a portion of the tines 4 lie substantially flat against the septum wall 38, less surface area of the clip 2 may be exposed to

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the patient's blood. Typically, a patient that receives a clip 2 may be administered anti-coagulant drugs to counteract the clotting of platelets on the surface of the clip 2. By reducing the amount of surface area of the clip 2 that is exposed to the blood, clotting problems may be reduced. Figure 11 shows a cross-sectional view of the septum wall 38 with the clip 2 in its relaxed state. Preferably, the clip 2 is designed such that the tines 4 of the clip 2 lie substantially flat against the septum wall 38 on either side of the septal defect 30.

Figures 10 and 11 further illustrate the septum wall 38 containing a septal defect 30 in which the defect is a hole-type structure 52 that may pass laterally through the septum wall 38 of a heart 32. In this regard, the septal defect 30 is similar to two overlapping flaps of tissue 40. This type of septal defect 30 may be seen, for example, in patients having a PFO. The clip 2 may be delivered in a similar way to the method described above. Specifically, the clip 2 may puncture the two overlapping flaps of tissue 40 while the clip 2 is in its stressed state and, upon relaxation, at least a portion of the hole-type structure 52 may collapse, thereby preventing the flow of blood across the septum wall 38.

In yet another embodiment of the invention, the clip 2 may have only a single tine 4. In its biased state, the clip 2 is substantially linear, as is shown, for example, in Figure 12. The clip 2 is deployed by piercing one or more flap(s) of tissue 40 such that a portion of the clip 2 is one side of a septum wall 38 and the remaining portion is on the opposing side of the septum wall 38. Both "halves" of the clip 2 then bend from a stressed state to a relaxed state to close the septal defect. The clip 2 in its relaxed state may take the shape of a "U" or "V" (shown, for example, in Figure 12), or even an "S" (shown in Figure 13). Figure 14 shows yet another embodiment of a clip 2 having a single tine 4. In this embodiment, the retaining end 6 of the clip 2 includes a head 7 that prevents the clip 2 from passing completely through the septum wall 38. In this regard, the clip 2, in its relaxed state, takes the shape of an "L". During deployment of this clip 2, the tine 4 is preferably advanced through the septum wall 38 until the head 7 prevents further advancement of the clip 2.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms

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or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.

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WHAT IS CLAIMED IS:

1. An apparatus for closing a septal defect, comprising:
a clip formed from an elastic material having at least two penetrating tines and an opposing retaining end, the clip being biased so as to project the at least two penetrating tines
5 distal to the opposing retaining end, wherein when the bias is removed, the at least two penetrating tines move laterally apart from one another.
2. The apparatus of claim 1, wherein the clip is formed from a superelastic material.
10
3. The apparatus of claim 1, wherein the clip is formed from a shape memory alloy.
4. The apparatus of claim 1, wherein the clip is formed from stainless steel.
15
5. The apparatus of claim 1, wherein the clip, in a stressed state, has a V shape.
6. The apparatus of claim 1, wherein the clip, in a relaxed state, has a W shape.
- 20 7. The apparatus of claim 1, wherein the clip, in a stressed state, has a U shape.
8. The apparatus of claim 1, wherein the clip is directed into a flap of tissue partially attached to a septum wall of a heart in the stressed state.
- 25 9. The apparatus of claim 1, wherein after the clip is directed into the septal defect, the clip transforms to a relaxed state wherein at least a portion of the tines lie substantially flat against a septum wall of the heart.
10. The apparatus of claim 1, further comprising:

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a tubular member comprising proximal and distal ends and a lumen therebetween, the distal end having a size for insertion into a blood vessel, the clip being carried within the lumen such that the penetrating tines are disposed distally to the retaining end; and

5 a pusher member slidably disposed within the lumen, the pusher member comprising a distal end disposed proximate the retaining end of the clip, the pusher member being moveable axially relative to the tubular member for ejecting the clip distally from the lumen.

11. The apparatus of claim 10, further comprising an actuator on the proximal end of the tubular member for advancing the pusher member relative to the tubular member.
10

12. The apparatus of claim 10, further comprising at least one axially disposed clip-retaining groove located in an inner surface of the tubular member.

13. The apparatus of claim 10, further comprising a notch located in the distal end of the pusher member for engaging the retaining end of the clip.
15

14. The apparatus of claim 10, further comprising an imaging device comprising an imaging element associated with the distal end of the tubular member.

20 15. The apparatus of claim 14, wherein the imaging device comprises an angioscope received within a lumen of the tubular member.

16. The apparatus of claim 14, wherein the imaging device comprises an elongate member comprising a distal end having a size for introduction into a body lumen.
25

17. A method of closing a septal defect within a patient's heart comprising the steps of:
providing a clip having at least two penetrating tines and an opposing retaining end;

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advancing the clip, in a biased state, through the patient's vasculature until the clip is disposed within the first chamber of the heart adjacent to the septal opening;

directing the at least two penetrating tines through a flap of tissue to expose the at least two penetrating tines to the second chamber of the heart;

5 moving the tines of the clip in laterally opposing directions so as to bring the flap of tissue into engagement with the septum wall to at least partially close the septal opening.

18. The method according to claim 17, wherein the tines of the clip are moved by removing the biasing force so as to permit the clip to transition to a relaxed state.

10

19. The method according to claim 18, wherein the clip is disposed within a distal end of a delivery apparatus comprising a catheter and a pusher member slidably coupled to one another, and wherein the step of advancing the clip comprises advancing the distal end of the delivery apparatus into the first chamber until the distal end is disposed adjacent to the
15 septal defect.

20. The method of claim 19, wherein the step of directing the first end of the clip through the flap of tissue comprises advancing the pusher member distally relative to the catheter, thereby ejecting the clip from within the delivery apparatus.

20

21. The method of claim 20, wherein the biasing force is removed by ejecting the clip from the delivery apparatus.

22. The apparatus of claim 1, wherein the clip is formed from NITINOL.

25

23. The method of claim 17, further comprising the step of imaging a portion of the heart.

24. An apparatus for closing a septal defect, comprising:

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A clip formed from an elastic material having a single penetrating tine and an opposing retaining end, the clip being biased so as to project the single tine distal to the opposing retaining end, wherein when the bias is removed, the clip transforms into geometric shape selected from the group consisting of "V", "U", "S", and "L".

5

25. The apparatus of claim 24, wherein the clip is formed from a superelastic material.

10

26. The apparatus of claim 24, wherein the clip is formed from a shape memory alloy.

27. The apparatus of claim 24, wherein the clip is formed from stainless steel.

15

28. The apparatus of claim 24, further comprising a head attached to the retaining end of the clip.

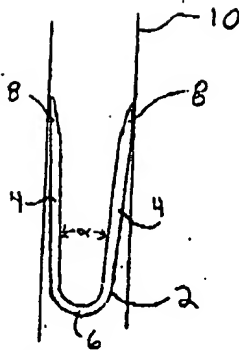


Fig. 1,

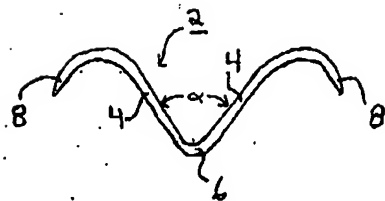


Fig. 2

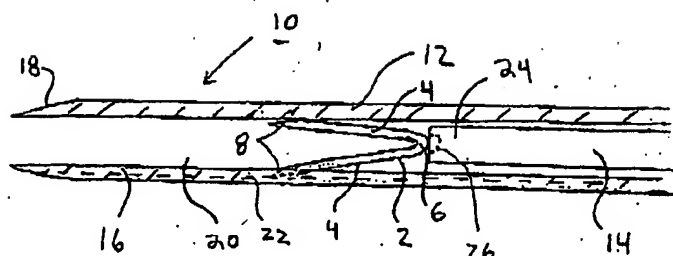


Fig. 3

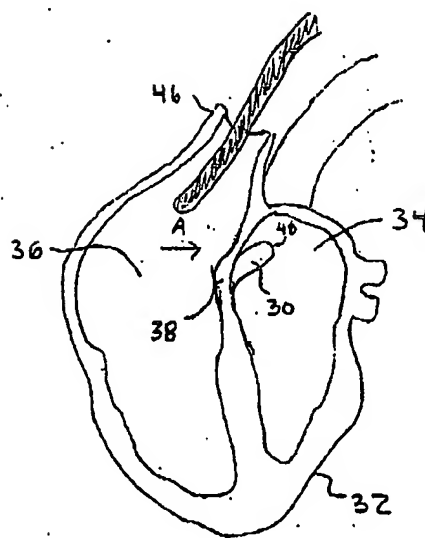


Fig. 4

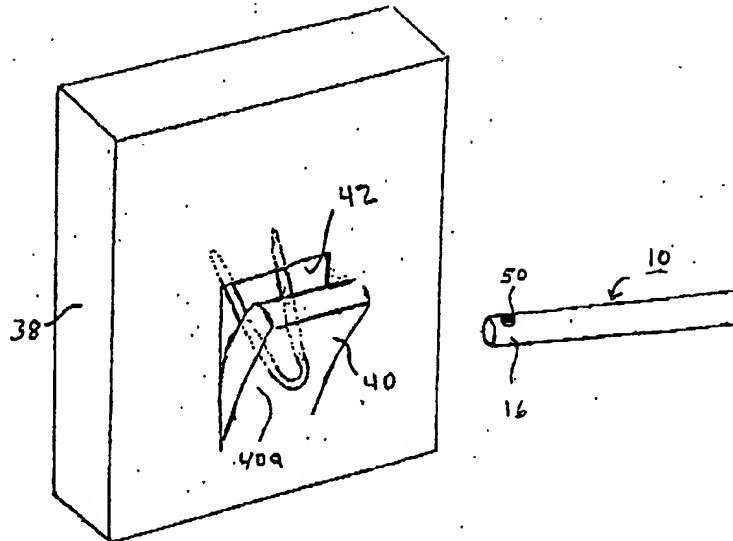


Fig. 5

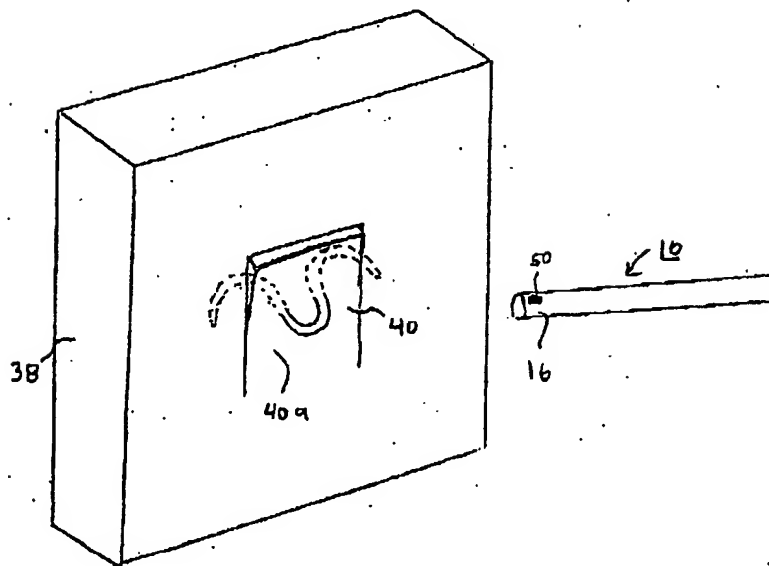
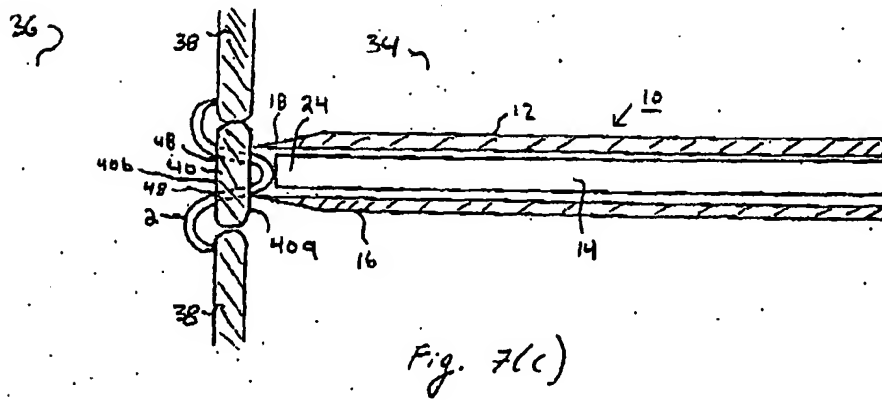
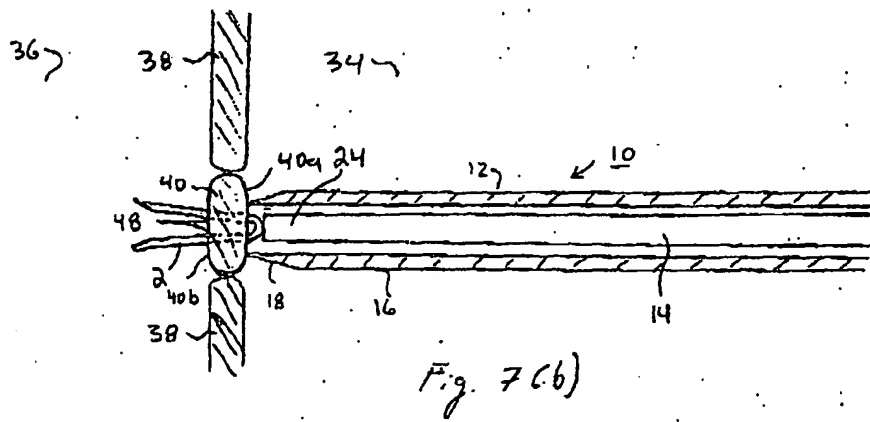
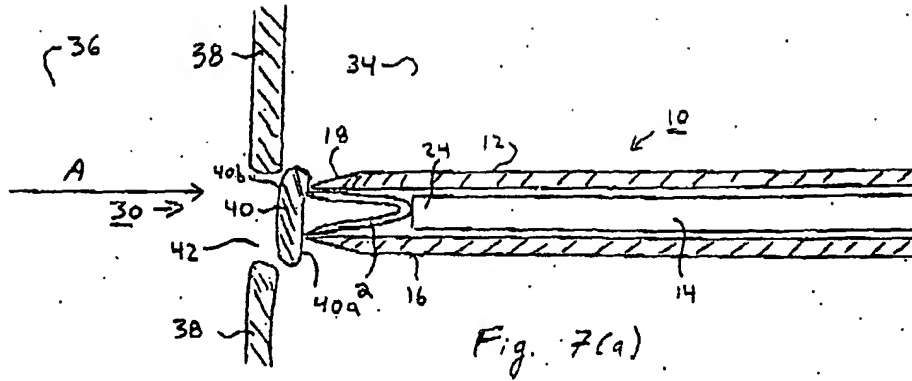


Fig. 6.



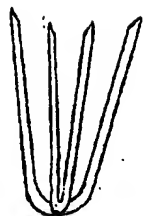


Fig. 8

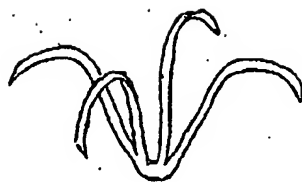


Fig. 9

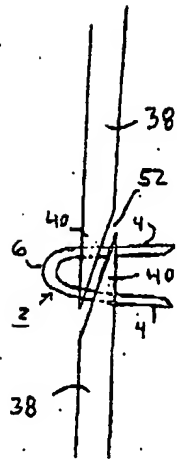


Fig. 10

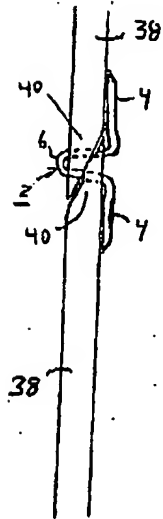


Fig. 11

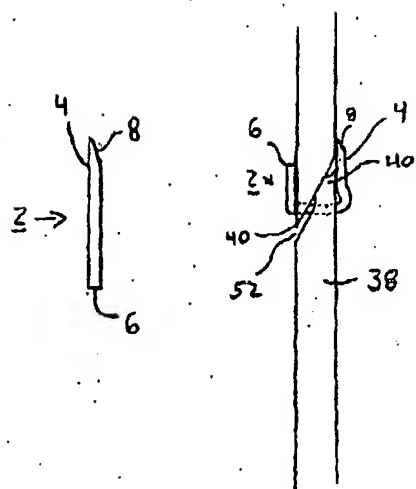


Fig. 12

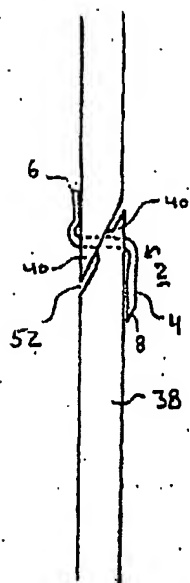


Fig. 13

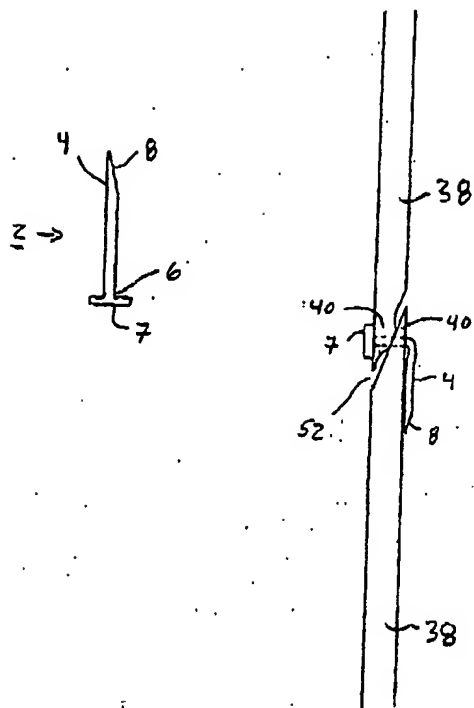


Fig. 14

INTERNATIONAL SEARCH REPORT

International Search No

PCT/US 02/28098

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B17/00 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 545 830 A (MAI) 9 June 1993 (1993-06-09) figures 1,2 ---	1-7
X	WO 00 07506 A (ANSON) 17 February 2000 (2000-02-17) the whole document ---	1-7, 10-16, 24-28
X	GB 2 359 024 A (ANSON) 15 August 2001 (2001-08-15) figures 1-6 --- -/-	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

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Date of the actual completion of the international search

17 February 2003

Date of mailing of the international search report

26/02/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

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Barton, S

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/28098

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SU 1 584 913 A (TOMSK) 15 August 1990 (1990-08-15) column 3, line 11 - line 27; figures 1,2 & DATABASE WPI Derwent Publications Ltd., London, GB; AN 1991-108122 TOME: abstract	1-7
X	EP 0 947 165 A (NISSHO) 6 October 1999 (1999-10-06) paragraph '0017! - paragraph '0019!; figures 1-4	1-5,10, 11
X	WO 00 40159 A (YEUNG) 13 July 2000 (2000-07-13)	24
A	figures 1,57	12
A	DE 94 13 645 U (SCHNEIDT) 27 October 1994 (1994-10-27) figures 1,3,4	13
A	EP 0 920 842 A (KRUCHININ) 9 June 1999 (1999-06-09)	
X	US 4 485 816 A (KRUMME) 4 December 1984 (1984-12-04)	24-28
A	column 6, last paragraph; figure 5	12

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

Continuation of Box I.2

Claims Nos.: 8,9

Claims 8,9 define their subject matter in terms of the use of the apparatus of claim 1 (such use being excluded under Rule 39.1(iv) PCT as a method for treatment of the human or animal body by surgery), rather than in terms of technical features necessary and sufficient to render the apparatus suitable for such use.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Internal application No.
PCT/US 02/28098

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 8, 9, 17-23
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☒ Claims Nos.: 8, 9
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US 02/28098

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 545830	A	09-06-1993	FR 2684289 A1 EP 0545830 A1	04-06-1993 09-06-1993
WO 0007506	A	17-02-2000	AU 5183499 A EP 1100381 A2 WO 0007506 A2 JP 2002522107 T	28-02-2000 23-05-2001 17-02-2000 23-07-2002
GB 2359024	A	15-08-2001	AU 3206201 A EP 1255491 A1 WO 0158363 A1	20-08-2001 13-11-2002 16-08-2001
SU 1584913	A	15-08-1990	SU 1584913 A1	15-08-1990
EP 947165	A	06-10-1999	JP 11276490 A EP 0947165 A1 US 6221092 B1	12-10-1999 06-10-1999 24-04-2001
WO 0040159	A	13-07-2000	AU 5924099 A CA 2358387 A1 EP 1139883 A1 WO 0040159 A1	24-07-2000 13-07-2000 10-10-2001 13-07-2000
DE 9413645	U	27-10-1994	DE 9413645 U1 DE 29500381 U1 EP 0698373 A2	27-10-1994 20-07-1995 28-02-1996
EP 920842	A	09-06-1999	RU 2108070 C1 AU 3364897 A EP 0920842 A1 US 6036716 A WO 9801086 A1	10-04-1998 02-02-1998 09-06-1999 14-03-2000 15-01-1998
US 4485816	A	04-12-1984	NONE	

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